

role or significance of the protein recited in the claims.

Applicants respectfully traverse the rejection.

As taught on page 60, lines 23-29 of the specification, antibodies raised against the polypeptide receptor of Fig. 4 are useful as an immunohistochemical diagnostic for monocytic cells and PBLs (peripheral blood lymphocytes) since it is known that such cells express the receptor of Fig. 4. This utility of the polypeptide receptor of Fig. 4 is supported by later published work on the tissue distribution of the receptor. Bleul, et al., Proc. Natl. Acad. Sci. (USA), 94: 1925-1930 (1997), hereafter "Bleul," newly cited, a copy of which is enclosed with the Supplemental Information Disclosure Statement submitted herewith, disclosed that an anti-CXCR4 monoclonal antibody (12G5) stained monocytes and lymphocytes from healthy donor plasma, as shown in the data of Table 1 on page 1927 of Bleul.¹ In addition, Bleul reported that CXCR4 expression was rapidly upregulated on peripheral blood mononuclear cells during phytohemagglutinin stimulation and interleukin-2 priming, as measured by immunofluorescent staining with 12G5 antibody and flow cytometry (see Figs. 3A and 3C on page 1928 of Bleul). Thus, Bleul demonstrated that antibodies against the polypeptide recited in the claims can be used to detect peripheral blood lymphocytes (such as T cells and B cells) or other peripheral blood mononuclear cells (such as monocytes), as taught in the specification.

The above-described use of antibodies against the polypeptide recited in the claims does not involve use of the recited polypeptide as the object of further research. Instead, the use of the antibodies for detection of PBLs in a tissue sample would enable the practitioner to identify and separate PBLs for further study or analysis of the PBLs. In this setting, the antibody/receptor system functions as a reagent or tool that permits the practitioner to isolate PBL cells for any purpose, such as use in medical diagnosis. Thus, the above-described use of antibodies against the polypeptide qualifies as a credible "real world" use which supports patentability under Brenner v. Manson (383 U.S. 519, 148 USPQ 689 (1966)).

Moreover, the rejection is not consistent with the grant of U.S. Pat. No. 6,087,475 to Lee et al. (granted on July 11, 2000). Claim 1 of U.S. Pat. No. 6,087,475 is drawn to the polypeptide receptor that is recited in claim 1 of the present application. In granting U.S. Pat. No. 6,087,475, the Office necessarily determined that the polypeptide claimed in claim 1 of the patent (and the polypeptide recited in the claims of the present application) satisfies the utility requirement under §101. As shown above, there is ample support for the Office's

¹ The chemokine receptor CXCR4 is now the most commonly accepted name for the polypeptide receptor of Fig. 4 in the application.

finding of adequate utility in connection with the polypeptide claimed in U.S. Pat. No. 6,087,475 (and recited in the present claims). Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §101.

Rejection under 35 U.S.C. §112, first paragraph

Claims 20-23, 25 and 27-33 are rejected under 35 U.S.C. §112, first paragraph as the application allegedly fails to adequately teach how to use the claimed invention for the same reasons cited in the §101 rejection.

Since the arguments presented in the discussion of the §101 rejection above also demonstrate how the disclosure of the application would have enabled one of ordinary skill in the art to use the claimed invention, Applicants respectfully submit that the claims meet the enablement requirement under §112, first paragraph and request that the rejection be withdrawn.

In light of the above, Applicants believe this application is in condition for allowance and earnestly solicit a Notice to that effect. If the Examiner has any questions concerning this response, he should not hesitate to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,
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